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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,977	03/13/2002	Takakazu Inoue	020159	2998

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EXAMINER
TUNG, JOYCE

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 04/10/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/006,997	Inoue
Examiner	**Art Unit**
Joyce Tung,	1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-14* is/are rejected.

7) ☒ Claim(s) *4 and 14* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892) ✓
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No.6,287,769. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-9 are drawn to a method of analyzing bacterial flora of a subject comprising amplifying the nucleic acid of an intestinal bacterial group and analyzing the intestinal bacterial flora on the basis of the amplified fragment via electrophoresis and probe hybridization. Claims 9-14 are drawn to an apparatus for analyzing an intestinal bacterial flora comprising a nucleic acid amplifier, an electrophoresis unit and analyzer. Claims 1-11 of U.S. Patent No.6,287,769 are drawn to a method of amplifying DNA from a source comprising amplifying a plurality of

different DNAs with each of plurality of primers. The method of U.S. Patent No.6,287,769 employs a reference primer having a known sequence to amplify a reference DNA. The method of U.S. Patent No.6,287,769 also includes an apparatus for amplifying DNA fragments comprising a body having a plurality of wells and a plurality of primers.

Since the phrase "amplifying nucleic acid of an intestinal bacterial group" in the instant claim is interpreted as that the intestinal bacterial group has a plurality of different DNAs and phrase "said specific primer is interpreted as that said specific primer has a plurality of primer molecules" in the instant claims, the method of the instant claims 1-9 is a species that would render obvious to the genus method claims 1-4 and 6-11 of U.S. Patent No.6,287,769.

Moreover, the phrase in claim 5 of U.S. Patent No.6,287,769, "a body having a plurality of wells" is interpreted as that the plurality of wells includes amplifier, an electrophoresis unit and analyzer. Thus, the method of the instant claims 10-14 is a species that would render obvious to the genus apparatus claims 5 and 6-11 of U.S. Patent No.6,287,769.

Thus, it is obviousness type of double patenting rejection.

3. Claims 1-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-17 of U.S. Patent No.6274306. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-9 are drawn to a method of analyzing bacterial flora of a subject comprising amplifying the nucleic acid of an intestinal bacterial group and analyzing the intestinal bacterial flora on the basis of the amplified fragment via electrophoresis and probe hybridization. The method of

claims 11-17 of U.S. Patent No.6274306 are drawn to a method of assaying microorganism employing the amplification of DNA from microorganisms and classifying the amplified DNA fragment by discrimination method.

Both the instant application and U.S. Patent No.6274306 have coincident scope. Thus, it is obviousness type of double patenting rejection.

Claim Objections

4. Claim 4 is objected to because of the following informalities: the phrase "a analyzing n" might be typographic error. Appropriate correction is required.

5. Claim 14 is objected to because of the following informalities: the claim language in claim 14 has grammatical error. Because it appears that claim 14 further limits to claim 13 in which the probe is amplified nucleic acid from intestinal bacterium with a PCR primer, the claim language does not express clearly on this issue. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. Claims 10-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 12-14 are vague and indefinite because of the phrase "derived from". It can not be determined whether or not the nucleic acid from the intestinal bacterial group is chemically modified or not since the phrase "derived from" applies to a chemical compound which is chemically modified. Clarification is required.

b. Claim 10 is vague and indefinite because of the phrase "an electrophoretic pattern fractionated in said electrophoretic unit". It is unclear whether the "electrophoretic pattern fractionated" is from said electrophoretic unit. Or there is another electrophoretic pattern fractionated from said electrophoretic unit. Clarification is required.

c. Claims 11-14 are vague and indefinite because of the phrase "hybridizes said amplified nucleic acid and a specific probe". It is unclear whether the amplified nucleic acid hybridizes to the specific probe. Clarification is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-2 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Hamad et al. (Journal of Applied Microbiology, 1997, Vol. 83, 764-770).

Hamad et al. disclose a method of studying microflora of Sudanese sorghum flour (See pg. 764, the Abstract). Seven strains of *Lactobacillus* were isolated, representing the dominant

flora (See pg. 764, the Abstract). The DNA was isolated from lactobacilli (See pg. 765 column 1, five paraph). RAPD-PCR was performed with an arbitrary primer (See pg. 765, column 1, seventh paragraph). The agarose electrophoresis patterns were visualized by ethidium bromide staining (See pg. 765, column 2, first paragraph).

Since the instant claims limit to "said specific primer is a primer having a specific amplification probability, the limitations of claims encompass the teachings of Hamad et al. that RAPD-PCR was performed with an arbitrary primer (See pg. 765, column 1, seventh paragraph) since all primers have specificity.

Furthermore, since Hamad et al. disclose that the partial sequences of the 16S rRNA of all three strains were found to be identical with that of *Lact. vaginalis* (See pg. 766, column 2, last paragraph), the 16S rRNA would have been amplified by using the same primer which amplifies *Lact. vaginalis*. The teachings of Hamad et al. anticipate that the primer used in said specific PCR primer which has a sequence capable of amplifying a nucleic acid region coding 16S rRNA of said intestinal bacterium.

Thus, the teachings of Hamad et al. anticipate the limitations of claims 1-2 and 9.

9. Claims 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilding et al. (5,498,392).

Wilding et al. disclose a device which including PCR reaction chamber (See column 3, lines 31-50). The device also has detection region to detecting the amplified polynucleotide (See column 3, lines 53-55, and column 4, lines 49-50). The device further includes gel

electrophoresis in detection region. The detect region may include a labeled binding moiety, such as a labeled polynucleotide capable of detectably binding with the amplified polynucleotide (See column 4, lines 45-60).

Since the claims is claiming an apparatus, the language "analyzing an intestinal bacterial flora" in the claim is a functional language, the functional language does not have patentable weight. Thus the teachings of Wilding et al anticipate the limitations of claims 10-11.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claim 3 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamad et al. (Journal of Applied Microbiology, 1997, Vol. 83, 764-770) as applied to claims 1-2 and 9 above, and further in view of Mullis et al. (4,800,159).

The teachings of Hamad et al. are set forth in section 8 above.

Hamad et al. do not disclose using a plurality of probes to hybridize to said amplified fragment and that the amplified nucleic acid is used as a probe for detecting an intestinal bacterial flora.

Mullis et al. disclose a method of polymerase chain reaction for synthesizing the desired nucleic acid sequence and detecting the sequence amplified (See the Abstract). The amplification products were detected by labeled probe (See column 3, lines 16-17).

The teachings of Mullis et al. suggest that the intestinal bacterial flora would have been amplified and detected by hybridizing a nucleic acid probe. The amplified nucleic acid would have been used as probe because the amplified nucleic acid would have the same specificity as the probe used for the detection.

One of ordinary skill in the art at the time of the instant invention would have been motivated to apply the probe used in the method of Mullis et al. to detect bacterial flora because using probes to hybridizing to an amplified nucleic acid products is more specific for detection. It would have been prima facie obvious to apply the probe to detect the amplified nucleic acid sequence of an intestinal bacterial flora in order to detecting the intestinal bacterial flora.

12. Claims 4-5, 7-8 and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamad et al. (Journal of Applied Microbiology, 1997, Vol. 83, 764-770) as applied to claims 1-2 and 9 above, and further in view of Wilding et al. (5,498,392).

The teachings of Hamad et al. are set forth in section 8 above.

Hamad et al. do not disclose using a detector on which said probe are arranged on specific positions in a detector for analyzing an intestinal bacterial flora.

Wilding et al. disclose a device for PCR which includes a detector. The detector has a probe located (See column 4, lines 52-55 and column 11, lines 56-61).

One of ordinary skill in the art would have been motivated to apply the device of Wilding et al. to the method of Hamad et al. for studying characterization of the bacterial flora. The motivation is that the device of Wilding et al. is for conducting a polynucleotide polymerization reaction to enable the rapid amplification of a polynucleotide in a sample and the device of Wilding et al. includes a detection region which would have been convenient for performing the detection without contamination. It would have been prima facie obvious to carry out the method of analyzing an intestinal bacterial flora via amplifying the DNA from the bacterial flora and hybridizing the amplified DNA with a specific probe. The method also employs a device for analyzing the intestinal bacterial flora.

Summary

13. No claims are allowable.

14. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

April 7, 2003

JEFFREY SIEW
PRIMARY EXAMINER
4/7/03